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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/411,863	10/04/1999	SHAMAY IZHAR	1620/3	8900

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EXAMINER
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ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/411,863	IZHAR, SHAMAY	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-57* is/are pending in the application.

4a) Of the above claim(s) *1-9,11-46,48 and 52-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47, 49-51 and 55-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. As requested in Paper No. 14, filed 7 August, 2002, claims 47, 49-51 and 55-57 have been amended. Claims 1-9 and 11-57 are pending. Claims 1-9, 11-46, 48, and 52-54 are withdrawn from consideration as being drawn to nonelected inventions. Claims 47, 49-51 and 55-57 are examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

3. The objection to claims 47 and 49 because of informalities is WITHDRAWN in light of amendment to the claims.

4. The rejection of claim 55 under 35 U.S.C. 102(b) as being anticipated by Vergunst et al is WITHDRAWN in light of amendment to the claim to state that the exogenes do not encode a recombinase.

Claim Objections

5. Claim 55 is objected to because of the following informalities:

Claim 55 lacks an article before "allelic" in line 6, and has an improper article before "genome" in line 3 (A genome is an inherent feature of a plant seed).

Claim Rejections - 35 USC § 112

6. Claim 55 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "wherein said first or said second exogenes do not encode a recombinase". Thus, such phrase constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

7. Claims 47, 49 and 56-57 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 8 February, 2002.

Applicant's arguments filed 7 August, 2002, have been fully considered but they are not persuasive. Applicant urges that Qin et al and Golic et al selected for progeny exhibiting active recombinase activity because they wanted plants with chromosomal instability. Applicant has submitted a copy of a PowerPoint presentation that presented data generated by using the instantly claimed method. Applicant states the data show that there were no unwanted recombinase events. Applicant urges that the instantly claimed method does not require the high FLP efficiency required by Gidoni et al because plants with the desired recombination events can easily be selected for (response pg 6-9).

This is not found persuasive. Gidoni et al teach that germinal transmission of the recombined loci is a pre-requisite for its use in the instant method (pg 155, left column, paragraph 2). Applicant has not presented data to dispute Gidoni's statement. Additionally, the instant claims do not require selection of a plant with the desired recombination events.

The PowerPoint presentation that is part of the Declaration of Dr. Yesodi was considered as much as possible; however, explanatory text in the presentation is minimal and the Southern blots were impossible to interpret, due to lack of explanation and poor fax quality. The declaration by Dr. Yesodi thus amounts to unsupported assertions. Applicant is invited to submit a Declaration in which the data is explained and in which the figures are clear.

Lastly, the claims are drawn to a method step of introducing a recombinase into a plant. The instant specification fails to provide guidance for topical application of a recombinase protein to a plant, for getting the applied protein into the plant, and for having it reliably result in specific recombination. The instant specification only provides guidance for introduction into a plant of a nucleic acid encoding a recombinase. In the response filed 7 August, 2002, Applicant did not provide an explanation for how topical application of the recombinase is enabled by the specification.

8. Claims 50-51 and 55 remain rejected and claims 47, 49 and 56-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 8 February, 2002.

The claims are broadly drawn to a multitude of plants having exogenic allelism and methods of using vectors comprising any of a multitude of genes to produce such plants. In contrast, the specification only describes the constructs in Figs 1 and 2 of the specification. Applicant does not describe other DNA molecules used by the methods or transformed into the plants, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

Because the sequences are not described, the method of using the sequences to produce plants with exogenic allelism is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the compositions used in the claimed methods, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

Applicant's arguments filed 7 August, 2002, have been fully considered but they are not persuasive. Applicant urges that selection of plants harboring specific DNA sequences can be easily effected using known molecular or biochemical techniques. Applicant refers to the PowerPoint presentation to show the generation of a plant characterized by exogenic allelism. Applicant urges that one distinguishing quality of the claimed plants is the allelic relationship of the two exogenes and that the plants could readily be typed by PCR or Northern blotting (response pg 9).

This is not found persuasive. The instant specification fails to describe the sequence of the promoters, transcribable polynucleotide sequences, and recombination sequences in these plants and fails to describe the specific phenotype of the plants themselves. The structural

features, *i.e.*, sequences, that distinguish all such plants from other plants are not provided. For example, the specification does not teach the structural features of the nucleic acid s that encode the polypeptides or RNA molecules that cause the plants to be male sterile and female fertile.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 47, 50 and 55-56 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Gutterson et al (US Patent 6,392,119, filed January, 1997).

Gutterson et al teach a method of generating exogenic allelism comprising crossing a plant comprising a construct comprising a first promoter, a first transcribable nucleic acid, and between the two a second transcribable nucleic acid operably linked to a second promoter, flanked by site-specific recombination sequences, to a plant comprising a nucleic acid encoding a recombinase to generate progeny in which the first promoter and the first transcribable nucleic acid are operably joined, and backcrossing the progeny to the first plant to generate progeny with exogenic allelism (Fig. 1 and column 8, line 59, to column 10, line 7). The method is used to produce male-sterile plants.

11. Claim 55 remains rejected under 35 U.S.C. 102(b) as being anticipated by Fabijanski et al. The rejection is repeated for the reasons of record as set forth in the Office action mailed 8 February, 2002.

Applicant's arguments filed 7 August, 2002, have been fully considered but they are not persuasive. Applicant urges that plants produced by the method of Fabijanski et al would not exhibit obligatory segregation of the two genes to different gametes (response pg 12-).

This is not found persuasive. This examiner is not in a position to evaluate the enablement of claims of an issued patent. The method of claim 9 of the issued patent states that it is one that produces seed wherein the first and second recombinant DNA molecules are located on opposite chromatids of homologous chromosomes such that segregation of the two recombinant DNA molecules occurs during meiosis. Thus, the method would generate plants that possess exogenic allelism, which the instant specification defines as positioning of two functionally distinct exogenes on the chromosomes of a chromosome pair such that substantially 100% segregation of the two exogenes is observed upon gamete formation (paragraph spanning pg 26-27).

12. Claims 49, 51 and 57 are free of the prior art, given the failure of the prior art to teach a method of backcrossing plants produced by a recombination system in which the plants have the construct described in claim 49 and given the unpredictability inherent in using these recombination systems, as detailed above.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who can be reached at (703) 308-0198.

Anne R. Kubelik, Ph.D.
October 9, 2002

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